

Exhibit 61

State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., Master Civil Action No. 01-12257-PBS, Subcategory Case No. 06-11337

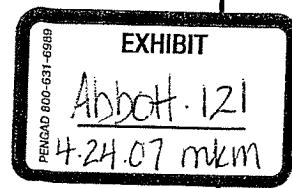
Exhibit to the January 15, 2010 Declaration of Philip D. Robben in Support of Defendants' Motion for Partial Summary Judgment
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Department of Health and Human Services
OFFICE OF
INSPECTOR GENERAL

**Cost Containment of Medicaid HIV/AIDS
Drug Expenditures**



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EXECUTIVE SUMMARY

PURPOSE

To compare the amount that Medicaid reimburses for HIV/AIDS drugs to the prices paid by other government purchasers.

BACKGROUND

Title XIX of the Social Security Act established Medicaid as a jointly-funded, Federal-State health insurance program to provide medical services to low-income persons. It is estimated that Medicaid's net spending on prescription drugs, the most frequently used benefit in the Medicaid program, totaled \$16.4 billion in fiscal year (FY) 2000. The Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration, spent \$617 million on antiretrovirals in FY 1999. Medicaid provides prescription drug benefits for 42 to 46 percent of the 335,000 persons living with HIV/AIDS who receive regular care.

As the largest source of public coverage for prescription drugs, Medicaid strives to be a prudent purchaser of pharmaceuticals. It does this by limiting drug reimbursement to pharmacies and by receiving quarterly rebates from drug manufacturers.

Other Federal programs also seek to limit pharmaceutical costs. To assess how Medicaid is functioning as a Federal purchaser of HIV/AIDS drugs, we compared Medicaid's net unit costs (reimbursement price minus rebates) for antiretrovirals in FY 2000 to other Federal purchasers. In particular, we compare Medicaid's net prices to: 1) Federal ceiling prices, 2) Federal supply schedule prices, 3) 340B Drug Pricing Program ceiling prices, and 4) the net costs paid under the 340B Drug Pricing Program rebate option available to AIDS Drug Assistance Programs.

FINDINGS

Medicaid pays up to 33 percent more than other Federal Government drug discount programs for HIV/AIDS drugs

Comparing the prices paid for antiretrovirals, we found that the 10 Medicaid agencies in our sample pay 33 percent more than the Federal ceiling price, 10 percent more than the Federal supply schedule and 15 percent more than the 340B Drug Discount Program ceiling prices. Medicaid's net costs also averaged 5 percent more than AIDS Drug Assistance Programs participating in the rebate option for most antiretrovirals.

Differences in Federal drug pricing formulas are partially responsible for cost discrepancies

The difference in HIV/AIDS antiretroviral drug costs across Federal programs is partially explained by the fact that each of the Federal purchasers we reviewed adheres to a different federally mandated formula. The intention of each of these approaches is to place limits on the prices of drugs procured by Federal purchasers. Yet, the outcomes of the various approaches differ and result in consistently higher antiretroviral drug prices for the Medicaid program.

State reimbursement formulas affect the magnitude of the gap between Medicaid and other government drug purchasers

State Medicaid agencies' flexibility in setting reimbursement rates has resulted in different prices for the same antiretroviral drugs among State Medicaid agencies. Massachusetts reports the lowest unit expenditures on pharmacy acquisition costs. If the other nine States in our sample utilized Massachusetts' formula, they could have saved an annualized \$24.5 million dollars. Georgia reports the highest unit expenditures on pharmacy acquisition costs.

Medicaid could have saved \$102 million if the 10 States surveyed purchased the 16 antiretrovirals at Federal ceiling prices

Comparing the actual per drug expenditures of Medicaid to what they would have paid if they had access to Federal ceiling prices results in a joint Federal/State savings of \$102 million in FY 2000 (\$54 million Federal share) for the 10 States in our review. This represents 25 percent of the total spent on antiretrovirals in these States. If all Medicaid programs were able to obtain Federal ceiling prices, we estimate the program could have saved \$140 million (\$73 million Federal share).

RECOMMENDATIONS

The rules guiding Medicaid reimbursement and rebates are intended to allow the program to participate in the pharmaceutical market as prudent buyers. Our findings demonstrate that Medicaid is paying more for antiretroviral drugs than other Federal purchasers. We offer several options regarding Medicaid drug reimbursement and rebates as potential means to lower Medicaid expenditures on antiretroviral drugs.

For the 16 HIV/AIDS drugs examined, Centers for Medicare and Medicaid Services should review the current reimbursement methodology and work with States to find a method that more accurately estimates pharmacy acquisition cost

In order to maximize scarce Federal and State dollars, it is essential to improve the accuracy of States' estimated pharmacy acquisition cost. We offer the following three suggestions for improving reimbursement methodology:

- ▶ *Option 1:* Develop safeguards to protect Medicaid from average wholesale price (AWP) manipulations, or
- ▶ *Option 2:* Create national estimated acquisition cost for the States based upon the average manufacturers price, or
- ▶ *Option 3:* Share average manufacturer price data with States so that they can accurately set Medicaid reimbursement amounts.

Whichever method CMS adopts to improve estimated acquisition cost, a re-examination of the dispensing fee should also be conducted to ensure that pharmacists can cover their costs.

The Centers for Medicare and Medicaid Services should initiate a review of Medicaid rebates for the 16 HIV/AIDS drugs examined

Though an improved reimbursement methodology would generate program savings, it would not completely close the gap between Medicaid and other government drug purchasers. This would require a more substantial rebate from drug manufacturers. We offer the following two suggestions to CMS for further research:

- ▶ *Option 1:* Increase the rebate percentage of average manufacturer price, or
- ▶ *Option 2:* Base the rebates on average wholesale price rather than average manufacturer price.

While our findings and recommendations pertain only to antiretroviral drugs, numerous other Inspector General reports have concluded that Medicaid pays more than other Federal and private purchasers for a wide variety of drugs. As part of a larger effort to examine the problems plaguing Medicaid drug reimbursement and rebate policies, our recommendations build off the recommendations made in those previous reports. Future work in this area may, in turn, find that the recommendations presented in this report for antiretroviral drugs may have broader applicability.

AGENCY COMMENTS

The CMS provided comments on the draft report in which they agreed with the overall intent of our recommendations, but expressed reservations with many of the specific suggestions we offered for achieving them. Primarily, CMS felt that they did not have the statutory authority to make the suggested changes. Since reducing Medicaid prices for HIV/AIDS medications is so crucial to ensuring access to these drugs, we encourage CMS to seek any legislation necessary to accomplish the task. However, we continue to believe that most of the options delineated in the report can be undertaken without amending current law. The complete text of CMS's comments can be found in Appendix E. Additional discussion can be found on page 26.

TABLE OF CONTENTS

	PAGE
EXECUTIVE SUMMARY	i
INTRODUCTION	1
 FINDINGS	
Medicaid Pays 33 Percent More than other Federal Programs for HIV/AIDS Medications ..	11
Differences in Drug Pricing Formulas Partially Responsible for Cost Discrepancies	12
Reimbursement Formulas Affect Magnitude of the Gap	14
Medicaid Could Have Saved \$102 Million	16
RECOMMENDATIONS	18
AGENCY COMMENTS	26
 APPENDICES	
A: Glossary of Terms	29
B: List of Antiretroviral Drugs	30
C: Sampled States' Formula for Estimating Acquisition Cost	31
D: Sampled States' Dispensing Fees	32
E: Agency Comments	33
F: Related Office of Inspector General Report Summaries	37
G: Related Office of Inspector General Reports	40
H: End Notes	41

INTRODUCTION

PURPOSE

To compare the amount that Medicaid reimburses for HIV/AIDS drugs to the prices paid by other government purchasers.

BACKGROUND

Medicaid

Medicaid is the largest program providing medical services to America's poorest people and represents our nation's primary health care safety net for low-income women, children and disabled persons. Title XIX of the Social Security Act established Medicaid as a jointly-funded, Federal-State health insurance program. The Federal Government contributes a matching percentage of State Medicaid outlays, ranging from 50 percent to 83 percent of health care costs, depending on the State's relative per capita income.

The Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA), administers Medicaid at the Federal level. The CMS estimates expenditures for the program totaled \$201 billion in fiscal year (FY) 2000, \$114 billion in Federal and \$87 billion in State funds. This funding covered approximately 41 million individuals.

Medicaid and HIV

Of the total \$201 billion Medicaid spent in FY 2000, \$4.1 billion went for HIV/AIDS care.¹ The States' portion of expenditures for Medicaid HIV/AIDS patients was \$1.9 billion. Federal Medicaid HIV/AIDS spending was \$2.2 billion.

There are an estimated 800,000 to 900,000 Americans living with HIV/AIDS, 300,000 of whom are estimated to be living with AIDS. Fifty-five percent of all adults and 90 percent of children with AIDS are enrolled in Medicaid.

Most persons with HIV/AIDS who qualify for Medicaid coverage do so by meeting one of two eligibility requirements. First, many individuals with HIV/AIDS become disabled as a result of their illness. This disability, combined with limited income, makes them eligible for Social Security Income, and consequently, eligible for Medicaid. Second, people with HIV may meet categorical and financial tests unrelated to their disease. Despite Medicaid's critical role in providing care for both HIV and AIDS patients, eligibility for the largest population of HIV infected persons, childless adults that have not yet been disabled by AIDS, is limited.

Medicaid eligibility may be broadening for persons infected with HIV. Since 1997, CMS has granted States the ability to submit a 1115 waiver proposal to test Medicaid eligibility expansion. In February 2000, Maine received approval to extend Medicaid benefits to non-disabled persons living with HIV. In January 2001, Massachusetts also received waiver approval to enable people with HIV to qualify for comprehensive health coverage under Medicaid. In 1999, Section 204 of the Ticket to Work and Work Incentives Improvement Act established the Demonstration to Maintain Independence and Employment grant program. This program authorizes States to provide Medicaid benefits and services to workers who have physical or mental impairments that, without medical assistance, will result in disability. Thus far, Mississippi has been granted \$27.5 million to provide Medicaid coverage to 500 persons living with HIV/AIDS. Finally, Congress is considering national legislation to provide States with an option to extend Medicaid coverage to low-income non-disabled individuals with HIV/AIDS without the need to apply for an 1115 waiver.

Medicaid and Prescription Drug Coverage

Medicaid is the largest source of public coverage for prescription drugs. It is estimated that Medicaid's net spending on prescription drugs, the most frequently used benefit in the Medicaid program, totaled \$16.4 billion in FY 2000. Medicaid provides prescription drug benefits for 42 to 46 percent of the 335,000 persons living with HIV/AIDS who receive regular care. In FY 1999, Medicaid spent \$617 million for antiretrovirals.

Medicaid's prescription drug program faces increasing demand and rising pharmaceutical costs. The rate of HIV infection is accelerating among low-income persons, especially women. In the last decade the proportion of AIDS cases reported among women has tripled.² Demand for services has also increased due to Medicaid eligibility expansion. Further, pharmaceutical costs have been increasing approximately 16 to 21 percent annually compared to the 4 to 7 percent annual increases in overall Medicaid spending.³ As a result of increasing demand and increasing costs, containment of prescription drug expenditures has become an important issue at both the State and Federal level.

Currently, Medicaid seeks to control pharmaceutical expenses in several ways. One way is to limit drug coverage through such measures as prescriptions limits and restrictions on specific drugs based upon drug formularies.⁴ However, Medicaid's ability to use formularies is limited. In particular, CMS issued a letter in June 1996 to State Medicaid directors requiring States to cover all Food and Drug Administration approved protease inhibitors, a prominent drug class used in the treatment of HIV/AIDS. States can also institute beneficiary co-payments, but these cannot exceed the maximum of \$3. Medicaid also strives to limit the cost of drugs. Toward this end, State agencies limit the amount they reimburse pharmacies for prescription drugs. They also receive rebates from manufacturers for dispensed drugs.

Medicaid Drug Reimbursement to Pharmacies

Under Section 1902(a)(30)(A) of the Social Security Act, CMS has the authority to set upper payment limits for services available under the Medicaid program. On July 31, 1987, CMS published the final rule (52 FR 28648) that limits Medicaid drug reimbursements to pharmacies. The guidelines for payment were issued to ensure that the Federal Government act as a prudent buyer of drugs.

The reimbursement methods set forth differ for generic and brand name drugs. All of the drugs in our study are brand name because there are no generic antiretrovirals available at this time. For brand name drugs, Medicaid reimbursement is the lower of either the pharmacist's usual and customary charge to the general public or the estimated acquisition cost (EAC) plus a reasonable dispensing fee.

Estimated Acquisition Cost

The estimated acquisition cost is the State agency's best estimate of the price generally paid by pharmacies for a drug.⁵ The CMS's final rule does not specify any particular method for calculating EAC. As a result, States have developed their own methods for estimating acquisition cost. States typically use one of two methods. The "cost plus" method calculates the provider's cost based upon the wholesaler acquisition cost (WAC) plus a markup percent. The WAC is the list price established by manufacturers for sales to wholesalers. The "list less" method relies upon the average wholesale price (AWP) less a discount percentage. The AWP is the manufacturer's suggested list price for a wholesaler to charge a pharmacy for a drug. Both the AWP and WAC are listed and updated by First Databank, a national drug pricing compendium, in the national drug product and pricing information publication the *Blue Book*.

The majority of State Medicaid agencies use the list less method. However, various investigations into AWP demonstrated that AWP was overstated by as much as 10 to 20 percent. In response, CMS clarified that the State determination of estimated acquisition cost using AWP must include a significant discount to be considered an acceptable estimate. In 1997, the Office of Inspector General (OIG) report, "Medicaid Pharmacy - Actual Acquisition Costs of Prescription Drug Products for Brand Name Drugs" (A-06-96-00030) found that the actual acquisition costs for brand name drugs were still on average 18 percent lower than AWP. The average State discount in 1999 was 10.4 percent off of AWP.⁶

Recent investigations conducted by the Department of Justice, the Office of Inspector General and Medicaid Fraud Control Units are further calling into question AWP's validity. They have found that even with the "significant discount" off of average wholesale price, prices paid by Medicaid are still inflated. As a result, efforts are being made to ensure accurate drug pricing data are used in setting Medicaid reimbursement rates. First Databank has agreed to change the way it reports prices for 48 pharmaceuticals based on figures that fraud investigators have determined to be closer to

what medical providers actually pay. None of the 48 pharmaceuticals with revised prices are antiretrovirals used for treating HIV/AIDS.

Dispensing Fees

State agencies are required to determine reasonable dispensing fees, or, if dispensing fees are not paid separately, to impute an amount equivalent to a reasonable dispensing fee. This fee represents the charge for the professional services provided by a pharmacist when dispensing a prescription. Prior to 1987, States were required to survey dispensing fee costs and update those fees in a periodic manner. The requirement was eliminated with the expectation that States would continue to work to establish a reasonable dispensing fee level and document these in their State plan.

Manufacturer Rebates: The Medicaid Drug Rebate Program

In addition to limiting reimbursement, the Medicaid program controls costs by obtaining rebates from drug manufacturers. The Omnibus Budget Reconciliation Act of 1990 created the Medicaid Drug Rebate Program. This Federal statute mandates that drug manufacturers provide rebates to State Medicaid agencies. For their drugs to be eligible for Medicaid reimbursement, manufacturers must enter into rebate agreements with the Secretary of the Department of Health and Human Services and pay quarterly rebates to the State Medicaid agencies.

Rebates are calculated separately for generic drugs and brand name drugs. The rebate for brand name drugs is the greater of 15.1 percent of the average manufacturer price (AMP) per unit or the difference between the AMP and the manufacturer's "Best Price." The average manufacturer price is the average unit price paid to the manufacturer for the drug by wholesalers. The Best Price is defined as the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity, excluding any prices charged to certain government agencies and the Federal Supply Schedule, State pharmaceutical assistance programs, and any single award contract prices.⁷ In an effort to restrain drug price inflation, the rebate calculation includes an additional rebate on any drug whose price increases at a rate faster than the Consumer Price Index-Urban.

Other Federal Drug Purchasing Systems

Department of Veterans Affairs

The Veterans Health Care Act (VHCA) of 1992, Section 603, states that prices to the Department of Veterans Affairs (VA), Department of Defense, the Coast Guard and the Public Health Service, known as the Big 4, may not exceed 76 percent of the non-Federal average manufacturer price (non-FAMP). The non-FAMP is the manufacturers weighted average of commercial, non-Federal sales per unit. These statutorily discounted prices

are typically referred to as the Federal ceiling prices. The law additionally requires that the Big 4 access these Federal ceiling prices through the Federal supply schedule (FSS).

In addition to calculating the Federal ceiling price, the VA manages several Federal supply schedules dealing with health care commodities for the entire Federal Government, including Schedule 65 I B for pharmaceuticals. The FSS provides a schedule of contracts and prices for a broad range of drugs that allow agencies to purchase various quantities of pharmaceuticals while still obtaining the discount associated with bulk purchasing. Using competitive procedures, contracts are awarded to companies to provide drugs at “the most favored customer price.”

340B Covered Entities

Section 602 of VHCA enacted Section 340B of the Public Health Services Act. This sets statutory ceiling prices for pharmaceuticals purchased by certain covered entities. The entities eligible for 340B Drug Discount Program direct purchase option purchase drugs directly from the manufacturers through a centralized mechanism. The ceiling price formula is roughly the average manufacturer’s price decreased by the Medicaid unit rebate amount (URA).

Among those eligible for the 340B Drug Discount Program are the AIDS Drug Assistance Programs (ADAP), established by the Ryan White Comprehensive AIDS Resource Emergency Act of 1990. The ADAPs provide medications to low-income individuals living with HIV/AIDS who have limited or no coverage from private insurance or Medicaid.

The 340B ceiling price is available to 23 State ADAPs who acquire pharmaceuticals through a centralized purchaser. Another 24 State ADAPs take advantage of a rebate option that allows them to access Medicaid unit rebates on a quarterly basis. Like Medicaid, these ADAPs do not purchase their own drugs but rather reimburse retail pharmacies for prescriptions filled.

Pharmaceutical Industry Overview

The pharmaceutical industry is extremely complex, including a myriad of arrangements that differ by drug, company and purchaser. Chart 1 provides an extremely basic view of these interactions. It is only meant to explicate the fundamental dynamics among the various entities involved in Medicaid drug purchasing and distribution. It does not, by any means, capture the full complexity of the system. The following paragraphs explain the chart from top to bottom.

Manufacturers typically do not distribute their products, but rather rely on wholesalers to warehouse and distribute their drugs. For brand name drugs, manufacturers set the wholesale acquisition price as a list price for wholesalers to purchase drugs from manufacturers. Manufacturers also set the average wholesale price as a suggested list

price for wholesalers to charge drug suppliers. Both the WAC and the AWP operate as suggested list prices and are typically not what is paid. Buyers negotiate lower prices through the inclusion of discounts, rebates or free goods.

Wholesalers purchase large quantities of drugs from manufacturers and distribute them to drug suppliers, including retail pharmacies, pharmacy benefit managers, hospitals and physicians. Almost 80 percent of all prescription drugs are purchased through wholesalers. The interaction between these components and the Medicaid program has been diagrammed in Chart 1 below. We have also included a glossary of terms in Appendix A.

Chart 1: Pharmaceutical Industry

Manufacturers

Manufacturers distribute their products primarily through drug wholesalers but also sell directly to pharmacies, hospitals and other bulk purchasers.

Manufacturers establish **wholesale acquisition cost** and **average wholesale price**.

↓ List Price: **Wholesale Acquisition Cost (WAC)**

↓ Actual Selling Price: **Average Manufacturers Price (AMP)**

Wholesalers

Wholesalers act as the middlemen that distribute pharmaceuticals from manufacturers to pharmacies.

↓ List Price: **Average Wholesale Price (AWP)**

↓ Actual Selling Price: **Actual Acquisition Cost (AAC)**

Retail Pharmacies

Pharmacies dispense prescriptions to consumers and provide professional pharmacist services.

↑ Reimbursement: **Estimated Acquisition Cost (EAC) - (WAC plus a percentage or AWP minus a percentage) - plus dispensing fee**

Manufacturer Rebates:

15.1% of AMP or AMP-Best Price

Medicaid Agencies

Cover the pharmaceutical costs for eligible low-income women, children and disabled.

Related Work by the Office of Inspector General

The Office of Inspector General has issued a significant body of work related to all aspects of Medicaid drug pricing including reimbursement, rebates and the accuracy of AWP. In 1997, the OIG released a series of reports specific to 10 States estimating the difference between AWP and the prices at which pharmacies purchase brand name and generic drugs. The results from the 10 States are summarized in two reports: "Medicaid Pharmacy: Actual Acquisition Cost of Generic Prescription Drug Products" (A-06-97-00011) and "Medicaid Pharmacy: Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs" (A-06-97-00030). These reports found that pharmacies pay an average of 42.5 percent less than AWP for generic drugs and 18.3 percent less for brand name drugs. The OIG recommended that CMS work to ensure that the States reimburse the ingredient portion of Medicaid in a manner more consistent with the findings of the report. It was also recommended that CMS study any of the other factors, such as dispensing fees, which they believe could significantly impact pharmacy reimbursement.

Other related reports include "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs" (A-06-97-00052). This report examines the disparity inherent in the fact that Medicaid drug rebates are calculated using the AMP while the Medicaid program reimburses pharmacies based on AWP. The Inspector General recommended a legislative change to base rebates on the AWP. In "Medicaid Drug Rebates: The Health Care Financing Administration¹ Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program" (A-06-91-00092), the OIG found manufacturers' calculations of AMP to be inconsistent. The OIG recommended that CMS should survey manufacturers to identify the various calculation methods used to determine AMP and develop a more specific policy for manufacturers.

Another related OIG report looks at the prices paid for 10 antiretrovirals by the AIDS Drug Assistance Program (ADAP). This report, "AIDS Drug Assistance Program Cost Containment Strategies" (OEI-05-99-00610), found that ADAP ceiling prices are, on average, 16 percent higher than the Federal ceiling prices and that ADAPs could have saved \$58 million in 1999 if they were able to access the Federal ceiling prices.

SCOPE AND METHODOLOGY

This inspection compares the net prices (reimbursement price minus rebates) that 10 State Medicaid agencies paid for all 16 HIV/AIDS antiretroviral drugs to the prices paid by other government purchasers. Specifically, the prices paid by the State Medicaid agencies were compared to the Federal ceiling prices, the Federal supply schedule contract prices, and the prices available to 340B eligible entities.

¹ In June 2001, the Health Care Financing Administration (HCFA) was renamed the Centers for Medicare and Medicaid Services (CMS).

The 10 States selected accounted for 73 percent of Medicaid's total fee-for-service spending on antiretrovirals in FY 1999. They also accounted for nearly 70 percent of all AIDS cases in the United States (excluding Puerto Rico).⁸ The States are: California, Florida, Georgia, Illinois, Maryland, Massachusetts, New Jersey, New York, Pennsylvania and Texas.

We selected the most commonly prescribed package size for each of the 16 Food and Drug Administration approved antiretroviral drugs. A list of these selected drugs can be found in Appendix B. Antiretrovirals constitute one of the most prescribed and effective drug therapies for treating HIV/AIDS and are covered by all Medicaid agencies.

We focused on the pharmaceutical prices paid by the fee-for-service component of Medicaid. We did not consider drug prices negotiated by Medicaid managed care organizations. Most States carve out HIV/AIDS prescription drug payments from their managed care contracts and pay for these drugs separately under their standard drug benefit policy. Furthermore, managed care organizations negotiate their own drug discounts with manufacturers and are not covered by Federal laws that seek to contain Medicaid drug costs.

For the purpose of this study, we focused on drug acquisition costs. For Medicaid, we defined these as the net costs to Medicaid for antiretroviral drugs. This is calculated by subtracting the manufacturer's rebates paid to Medicaid from the reimbursement rates paid by Medicaid to the pharmacies. We selected acquisition cost, choosing to disregard administrative overhead, drug distribution and storage expenses, in order to control for different administrative and drug distribution systems. Comparisons incorporating this data would amount to a comparison of alternate systems and are not the focus of this study.

To conduct our analysis, we gathered information regarding pharmaceutical pricing from CMS and the VA. The CMS supplied us with the average manufacturer's price, the Best Price, the Medicaid unit rebate amount, 340B ceiling prices as well as total expenditures on antiretrovirals. The VA provided us with data on the Federal ceiling prices and the FSS contract prices.

To gather data on actual State Medicaid agencies' expenditures, we sent a survey to each of the 10 States in our sample in September 2000. The survey requested States to record drug reimbursements, rebates and dispensing fees for the first two quarters of Federal FY 2000. The survey also asked States brief questions concerning the reimbursement formula, dispensing fee charges, and any additional rebates. Finally, the States were requested to provide the total amount spent on the 16 drugs in FY 1999.

The surveys were followed up with telephone interviews with each State's Medicaid Director or Pharmacy Division Director. The purpose of the interviews was to gain a general understanding of program operations and to explore any efforts surrounding

HIV/AIDS treatment or drug cost containment strategies. The interviews were conducted between September and November of 2000.

We have taken precaution not to disclose any proprietary drug prices. Towards this end, most estimates are averages and all estimates have been rounded. All savings estimates based on this information have been annualized. We conducted our review in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

Medicaid pays up to 33 percent more than other Federal Government drug discount programs for HIV/AIDS drugs

Comparing the prices for antiretrovirals, we found that the Medicaid agencies we sampled pay up to 33 percent more than other Federal Government programs that purchase antiretrovirals. On average, Medicaid pays:

- 33 percent more than the Federal ceiling price,⁹
- 10 percent more than the Federal supply schedule contract prices, and,
- 15 percent more than the 340B Drug Discount Program ceiling prices.

On average, Medicaid will pay 61 cents more per pill than the Big 4 agencies covered by the Federal ceiling prices. This difference ranges from 7 cents more per pill for Rescriptor and \$1.10 more per pill for D4T. For D4T, this difference translates into \$66 more per prescription.

While Medicaid's average net price is higher than the Federal Supply Schedule average price when all 16 drugs are considered, for 7 drugs, Medicaid pays less than the FSS price. Medicaid averages 11 cents less per pill for these 7 drugs. However, where Medicaid is paying more than the FSS, they are averaging 50 cents more per pill. For example, Medicaid pays 46 percent more for D4T than agencies accessing the FSS and 44 percent more for Videx.

These comparisons indicate that the Medicaid program is not as successful as other Federal purchasers in securing low-cost pharmaceuticals for its recipients. One possible explanation for the discrepancy is the fact that the various programs purchase their drugs at different points in the economic chain of pharmaceutical manufacturers, wholesalers and pharmacies. The VA, on behalf of the Big 4 and the rest of the agencies accessing the FSS, as well as the 340B Drug Discount Program (direct purchase option) purchase directly from manufacturers or wholesalers. The Medicaid program does not purchase drugs directly. Rather, participating pharmacies bill Medicaid an allowed amount for filled prescriptions.

Given that Medicaid's price purchases the additional services of a pharmacist, it is not surprising that Medicaid's reimbursement rate is higher than other program's purchase prices. The National Association of Chain Drug Stores found that in 1999, 22 percent of the cost of a prescription went to the pharmacy and another 2.3 percent went to the wholesaler. However, the prices used in the above comparisons were not Medicaid's reimbursement prices, but rather its net prices. Medicaid's net price is their reimbursement price minus manufacturer rebates. The rebates are intended to give

Medicaid the benefit of price discounts offered by the manufacturers to their largest customers. Even calculating in these rebates, Medicaid is paying the highest prices for antiretrovirals of any Federal purchaser.

Medicaid pays 5 percent more for antiretrovirals than AIDS Drug Assistance Programs with identical drug distribution structure

While the above comparisons may only approximately gauge Medicaid's drug purchasing performance due to differences among the programs, one would expect Medicaid to pay the same amount for the same drugs when compared to a government program of similar structure. In order to assess this, we compared the prices Medicaid pays for antiretrovirals to those paid by AIDS Drug Assistance Programs utilizing the rebate option of the 340B Drug Discount Program.

The Medicaid program and the rebate ADAPs share identical drug purchasing and distribution structures. Like Medicaid, rebate ADAPs reimburse pharmacies for the purchase and distribution of drugs. Like Medicaid, rebate ADAPs receive the Medicaid unit rebate from manufacturers on a quarterly basis. Despite their identical structures, Medicaid paid, on average, 5 percent more than the drug assistance programs for 10 antiretrovirals in 1999. Medicaid reimburses 6 percent more for Combivir, Videx and Retrovir. Since both programs receive the same statutorily defined rebates, the discrepancy indicates that Medicaid's reimbursement rate for the sampled States is higher than the average reimbursement rate for the rebate ADAPs.

Differences in Federal drug pricing formulas are partially responsible for cost discrepancies

Each Federal drug purchaser adheres to a different federally mandated formula to contain drug costs. The Big 4 and the 340B programs, because they have the ability to purchase directly from a manufacturer or wholesaler, are able to realize their savings up-front through federally defined ceiling prices. Medicaid, on the other hand, attempts to contain costs by recouping rebates from manufacturers after paying discounted retail prices for pharmaceuticals. The intent of each approach is to place limits on the prices of drugs procured by Federal purchasers. Yet the outcomes of the various approaches differ and result in consistently higher prices for the Medicaid program. Table A outlines the formulas governing drug prices for the Federal programs of interest.

Table A. Federal Drug Discount Formulas

Drug Purchasing Program	Drug Purchasing Formula ¹⁰		Statutory Authority
	Reimbursement Base	Cost Containment Measure	
Medicaid	Wholesaler prices	15.1% of Manufacturer prices	Omnibus Budget Reconciliation Act 1990
Federal Ceiling Price	Manufacturer prices	24% of Manufacturer prices	Veterans Health Care Act of 1992 (Section 603)
Federal Supply Schedule	'most favored customer price'	annual negotiations with manufacturers	Federal Property and Administrative Services Act of 1949
340B Drug Discount Program (direct purchase)	Manufacturer prices	15.1% of Manufacturer prices	Veterans Health Care Act of 1992 (Section 602)
340B Drug Discount Program (rebate option)	Wholesaler prices	15.1% of Manufacturer prices	63 CFR 35239

As shown in Table A, there are several considerations when comparing Federal drug pricing formulas. One is the price estimate used as the base reimbursement amount, a second involves the calculation of those base estimates, and a third is the level of the mandated discounts.

Medicaid and rebate ADAPs reimburse based on a wholesale list price. This is a recommended list price for the sale of drugs from wholesalers to retailers. On the other hand, the Federal ceiling price and the 340B ceiling price are sales calculated using manufacturer prices. As a result, Medicaid is at a disadvantage because its reimbursement formula is based on the wholesale list price, which is always higher than the manufacturer sales price. It is higher since it represents a price farther down the chain of buyers and sellers. It is also higher because wholesale list price is only a list price that is almost always higher than the actual purchase price, whereas manufacturer sales prices are based on actual transaction prices.

Second, even when measures for the various programs are based on manufacturers' prices, there are different interpretations of what that base includes. The VA bases its reimbursement and cost containment on the non-federal average manufacturer price (non-FAMP). Non-FAMP is the average price of a drug that is paid by wholesalers in the United States to the manufacturer, except for any prices paid by the Federal Government.¹¹ The CMS bases cost containment on average manufacturer price, which is the average price paid to the manufacturer for the drug by wholesalers for drugs distributed to the retail pharmacy class of trade.¹² Although conceptually similar, these definitions are not identical, and CMS and the VA may calculate them slightly differently. Both AMP and non-FAMP specifically exclude sales to federal purchasers, but how they may vary is unclear. Furthermore, the VA updates their non-FAMP calculation annually whereas CMS updates the AMP calculation quarterly.

Third, the level of discounting in the programs' cost containment measure also differs. Medicaid and rebate ADAPs receive the Medicaid unit rebate amount from manufacturers. This is roughly 15.1 percent of AMP. They receive these rebates quarterly only after reimbursing retail pharmacies at prices based on average wholesale price. The 340B Drug Discount Program also uses the Medicaid unit rebate amount to discount the cost of drugs, but there is a key difference between program formulas. The 340B direct purchase program subtracts the unit rebate amount (URA) from the drug price prior to the drug purchase. The Federal ceiling price provides an even steeper discount by subtracting 24 percent off of manufacturer prices rather than the 15.1 percent represented by the Medicaid unit rebate amount. Thus, Medicaid faces disadvantages in both paying a higher reimbursement base and receiving a lower cost containment discount when compared to Federal ceiling prices.

State reimbursement formulas affect the magnitude of the gap between Medicaid and other government drug purchasers

State Medicaid agencies have flexibility in setting their reimbursement rates. This has resulted in different prices for the same drugs among State Medicaid agencies. Massachusetts' net unit prices are 24 percent higher than the Federal ceiling prices for these 16 drugs. Maryland's approach yields net prices that are 33 percent higher than the Federal ceiling price. Georgia bears the highest net costs, which are 55 percent higher than the Federal ceiling price. Given the fact that Medicaid manufacturer rebates are nationally set by CMS, the only explanation for the difference among States is their reimbursement methodology.

As previously stated, Medicaid reimbursement of pharmacies includes two components, the estimated acquisition cost and the dispensing fee. The State Medicaid Manual defines estimated acquisition cost as "the agency's best estimate of the price generally and currently paid by providers."¹³ Currently, CMS grants States maximum flexibility in determining estimated acquisition cost. Seven of the 10 States calculate this estimate

based solely upon average wholesale price. Two States consider both average wholesale price and wholesaler acquisition cost and reimburse at the lower calculation. One State bases calculations solely upon WAC. Appendix C contains a list of the States' reimbursement formulas.

Massachusetts reports the lowest unit pharmacy acquisition costs

The other nine States reimburse pharmacies at an average unit price that is 2 to 16 percent higher than Massachusetts' cost for these 16 drugs. If the other nine States in our sample utilized Massachusetts' formula, they could have saved an annualized \$24.5 million. Of this total, over \$12.7 million represent the Federal share of program savings. These savings would narrow the disparity between State Medicaid net costs and Federal ceiling prices by 24 percent. The gap would close even further for the Federal supply schedule (58 percent) and 340B covered entities (44 percent).

Massachusetts is the only State in our sample that consistently calculates pharmacy reimbursement based upon wholesaler acquisition cost. The WAC represents the price at which wholesalers purchase the drug from the manufacturer. Massachusetts reimburses at WAC plus 10 percent. The other six States (not in our sample) that use WAC for constructing pharmacy costs also average a 10 percent mark-up.

Georgia reports the highest unit pharmacy acquisition costs

Georgia reimburses pharmacies at an average unit price that is 9 to 16 percent higher than the reimbursement of the other nine States. If Georgia utilized a reimbursement calculation equal to the average calculation of the other nine States, it could have saved over \$1.5 million in annual net costs. This represents a savings of 10 percent of Georgia's total net costs, of which the Federal Government pays a 60 percent share.

Georgia reports using AWP minus 10 percent as its formula and obtaining its pricing information from First Databank. Four other States in our sample also report the consistent use of the AWP minus 10 percent formula and the receipt of data from First Databank. The average drug cost for Georgia is over 9 percent higher than these other four States.

Eight of ten States pay modest dispensing fees

While the estimated acquisition cost calculation is intended to reimburse the pharmacies' costs to purchase the drug, the dispensing fee is meant to compensate pharmacies for the costs of dispensing the drug.

Most States pay pharmacists a flat dispensing fee for brand name drugs. These flat fees range from \$3.00¹⁴ to \$4.23. The average flat dispensing fee is \$3.89. Some States employ a "tiered" dispensing fee that varies across drugs. For two of these tiered-fee

States, the maximum dispensing fees average \$4.35. See Appendix D for a list of dispensing fees by State.

Illinois and Texas are the only States in our sample with significantly higher dispensing fees. Illinois pays a fee equal to 10.4 percent of the drug cost, up to a maximum fee of \$15.40. For 15 of the antiretrovirals, the calculated fee reached the Illinois cap, and the average fee for all 16 drugs was \$15.10. The Texas fee system pays \$5.27 plus 2 percent of the drug cost. This calculation produced an average fee of \$10.85 for Texas for the 16 drugs in our study.

Medicaid could have saved \$102 million if the 10 States surveyed purchased 16 antiretroviral drugs at Federal ceiling prices

The 10 States we reviewed would have saved a total of \$51 million or 25 percent¹⁵ of their net cost for the first two quarters of FY 2000 if their drug prices equaled the Federal ceiling prices. This amounts to program savings of \$102 million annually. The Federal share of this savings is approximately \$54 million annually.

While this savings estimate is limited to only 10 of the 52 Medicaid programs, the 10 States are those with the largest percentage of HIV/AIDS cases. These States also represent the bulk of Medicaid expenditures on antiretrovirals. We estimate that they represent 73 percent of the total Medicaid spent in FY 1999 for the 16 antiretrovirals. If we assume this same percentage for FY 2000, we can estimate that if all Medicaid programs' net prices were equal to the Federal ceiling prices, the program could have saved \$140.5 million, saving the Federal Government \$73.8 million.

The States that would save the most if Medicaid net costs were equivalent to other Federal drug prices are New York, Florida and California. This is due to the extremely large volume of drugs they purchase. These three States purchased 73 percent of all of the units purchased by our sample States. The States that would maximize per unit savings are Georgia, Texas and Illinois. On average, Georgia could save over a dollar per pill if their net prices were equal to the Federal ceiling prices. They could save 75 cents per pill if their net prices were equal to those listed on the Federal supply schedule.

Medicaid could have saved over \$55 million, representing over half of the total savings estimate, if their net prices for just 3 of the 16 drugs were equal to the Federal ceiling prices. If the net price of Combivir was equivalent to the Federal ceiling prices, the program would have saved \$26 million. Medicaid could have saved another \$18 million if D4T net prices were equivalent to the Federal ceiling prices and almost \$12 million on Epivir. The median savings for all 16 drugs is \$4 million.

These savings could be applied to the expanding need for antiretroviral therapy

All States have opted to include prescription drug benefits in their programs, so Medicaid covers antiretroviral therapy for all eligible persons with HIV/AIDS. Medicaid faces increasing demand for antiretrovirals because the population of Medicaid eligible persons with HIV/AIDS is growing. Program savings can be translated into the ability to provide life-saving antiretrovirals to additional persons for the same cost. The \$102 million savings could purchase additional antiretrovirals to meet the impending pharmaceutical needs and improve the lives of several thousand more individuals living with HIV/AIDS. Using the estimate of \$12,000 a year for combination antiretroviral therapy, the savings could purchase a complete regimen for over 8,500 HIV-infected persons.

Focusing solely on the three drugs with the most savings, Epivir, Combivir and D4T, also results in a substantial increase in purchasing power for these life-saving therapeutics. The \$102 million in savings could purchase an additional 728,000 bottles of D4T at Federal ceiling prices. This translates into a prescription of a bottle per month for 60,000 patients. Alternately, the \$102 million in savings could purchase 712,000 additional bottles of Epivir for 59,000 patients' annual needs or 315,000 bottles of Combivir for 26,300 patients.

This purchasing ability is particularly important for the Medicaid program in light of three trends. First, some States are considering extending Medicaid eligibility to low-income HIV-positive individuals before they become categorically eligible through disability. The CMS has already approved waivers for Maine and Massachusetts to conduct such demonstration programs, and other States have pending applications. States that apply for such demonstration waivers must prove budget neutrality, and decreased drug costs can help the States to extend prescription drug eligibility and still meet this requirement.

Second, the rate of HIV infection is accelerating among low-income persons, especially women. In the last decade the proportion of AIDS cases reported among women has tripled¹⁶. This trend suggests that more HIV-positive persons will become categorically eligible for Medicaid. Providing antiretroviral therapy to more persons without increasing total expenditures would ease the impending strain on Medicaid budgets.

Third, some States have already experienced budget strains and shortfalls related to Medicaid drug costs, and these pressures can have serious consequences for the provision of optional services. For example, the Medicaid Director of Indiana has proposed restricting Medicaid drug coverage and eliminating certain other optional services to avert budget shortfalls over the next 2 years.¹⁷ Cost savings for antiretrovirals represents one means to alleviate strained budgets and to preclude the need to restrict coverage of these lifesaving drugs.

RECOMMENDATIONS

Maximizing the ability to purchase life-saving antiretroviral drugs may be the only fiscally viable solution to meeting the challenges of increasing demand and access. Demand for HIV/AIDS pharmaceuticals continues to increase as the standard of care for persons living with HIV/AIDS grows increasingly reliant on drug therapy. The National Institutes of Health/Public Health Service *Guidelines for the Use of Antiretroviral Agents in HIV Infected Adults and Adolescents* calls for the use of combination therapy comprised of at least three drugs. Additionally, the numbers of HIV-infected people are climbing among the low-income, traditionally under-served, population. This, in combination with the fact that approximately 68 percent of the HIV/AIDS population in care has no private health insurance¹⁸ will continue to place increasing demands on Medicaid to provide more pharmaceuticals. Beyond this increase in demand, State and Federal legislatures continue to consider expanding Medicaid coverage to a broader range of HIV-infected persons.

The rules guiding Medicaid reimbursement and rebates are intended to allow the program to participate in the pharmaceutical market as prudent buyers. Our findings demonstrate that Medicaid is paying more for antiretroviral drugs than other Federal purchasers. Because of this discrepancy and the potential program savings, the CMS should revisit the rules governing Medicaid reimbursement and rebates for antiretrovirals.

Unfortunately, the extreme complexity of the pharmaceutical market complicates the resolution of these issues. The drug industry is multi-layered, with a variety of manufacturing, distribution and retail sales arrangements that not only differ by geographic location, but also by product. Thus, it is extremely difficult to determine how and to what degree changes will affect market participants. Recognizing the potential for unexpected impacts, we offer several options within each recommendation for CMS to examine as means to improve reimbursement and rebate methodology for antiretroviral drugs. Our recommendations suggest starting points for additional research and discussion on how these changes could impact quality and access to care. Such comprehensive examinations represent the first step to actuating the long term goals that involve regulatory or legislative changes.

For the 16 HIV/AIDS drugs examined, Centers for Medicare and Medicaid Services should review the current reimbursement methodology and work with States to find a method that more accurately estimates pharmacy acquisition cost

The CMS has the ability to address deficiencies in the Medicaid reimbursement system. Under Section 1902(a)(30)(A) of the Social Security Act, CMS has the authority to set upper payment limits for services available under the Medicaid program. Regulations 42 CFR 447.331 through 447.334 limit the aggregate amounts State Medicaid agencies may claim for pharmaceuticals. To be granted Federal matching funds to pay for pharmaceuticals, State agencies are required to submit claims to CMS for approval. In order to maximize scarce State and Federal dollars it is essential that CMS use its authority to help improve the accuracy of States' estimated pharmacy acquisition cost.

Options for Improving Estimated Acquisition Cost

Medicaid's current reimbursement system predominantly relies upon average wholesale price to estimate acquisition cost. The CMS can improve the EAC calculation either by making changes to AWP within the existing system or by changing the basis of the calculation. If CMS prefers to continue using AWP, then we suggest the following improvement option:

- ▶ **Option 1: Develop safeguards to protect Medicaid from average wholesale price manipulations**

The CMS has demonstrated an awareness of problems with AWP validity, and we encourage CMS to intensify its efforts to address this issue. In 1997 and 1998, CMS supported legislative proposals that would have required Medicare reimbursement to be based upon actual acquisition cost rather than average wholesale price. Also in 1998, in comments to an OIG report, "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs" (A-06-97-00052), CMS indicated that they were planning to examine the calculation of AWP. They stated that this review would include issues such as, "how AWP is defined; how to safeguard against manipulation of AWPs to maximize reimbursement or minimize rebates; how to verify the accuracy of AWPs; the need for an indexing factor; and differences in AWPs for brand name versus generic drugs."¹⁹ The CMS has not yet undertaken this examination, but we suggest that they follow through with their planned study. Such an examination would provide a solid foundation of knowledge for building safeguards to protect Medicaid from AWP manipulations.

More recently, CMS has expressed the intent to work with State Medicaid programs to implement a revised AWP methodology that the Department of Justice has established with First Databank regarding a limited set of drugs. One approach to revising the AWP methodology would be for CMS to require EAC calculations using AWP to be based on market surveys in order to qualify for Federal financial participation. Providing clear guidelines for acceptable calculations will assist States in maintaining Medicaid's responsiveness to the pharmaceutical marketplace.

Furthermore, we suggest that CMS reinforce these guidelines by requiring a more frequent reporting of payment assurances by States. To access Federal matching funds, States must make "findings and assurances" that their drug reimbursements have not exceeded the maximum aggregate limits that CMS has established.²⁰ Payment assurances for brand name drugs compare the prices paid by State agencies to State calculations of estimated acquisition cost. The CMS set this reporting period for every 3 years to limit the burden on States to make these calculations. At the time of the regulation, however, CMS did not anticipate that States would use the EAC reimbursement method as consistently as they have. Submitting pricing assurances may be less arduous than anticipated because States already make estimated acquisition cost calculations. Increasing the frequency of these reports may increase accountability of State reimbursements without imposing an undue burden.

If CMS prefers to create a new basis for estimating acquisition cost, then we suggest that CMS use average manufacturer price for the EAC calculation. The CMS can either set national EAC levels or allow States to set their own levels. If CMS's main concern is protection of AMP confidentiality, then we recommend Option 2. If CMS is more concerned with State flexibility, then we recommend Option 3.

Option 2: Create national estimated acquisition costs for States based upon average manufacturer price

An alternative to creating a market-based average wholesale price may be to discontinue the reliance upon this figure. The use of AWP for estimating acquisition costs emerged as a matter of convenience because AWP data was readily accessible. Initially, it did not seem problematic to rely on manufacturer's pricing information without audit controls. Because manufacturers do not bill the program for their drugs, there appeared to be little to no incentive to inflate prices. However, over the years the financial link between manufacturers and Medicaid billers has become evident. Manufacturers can inflate AWP and generate financial incentives for providers to favor their products. Now that these issues have been identified, the negative repercussions of relying on AWP outweigh the convenience.

An alternate reimbursement option involves CMS determining its own estimated acquisition cost for States based upon average manufacturer price. Unlike AWP, which is a suggested list price, AMP is a calculation that reflects actual transactions between drug manufacturers and commercial purchasers. Manufacturers submit AMP information to CMS quarterly, which CMS uses to calculate Medicaid's unit rebate amounts. The average manufacturer price data is subject to Federal oversight and audits, which ensure its accuracy.

A reimbursement formula based on AMP instead of AWP would also serve to connect rebates and reimbursement. Currently, reimbursement is based on AWP and rebates are based on AMP, creating a disconnection between the two calculations. This disconnection has introduced incentives for manufacturers to inflate average wholesale price to generate profit for providers. If both rebates and reimbursement were based on AMP, however, the incentive to inflate reimbursement amounts would be removed as any increase to AMP would also cause an increase in the rebates paid by the manufacturer.

The confidentiality of AMP is statutorily protected, so States cannot currently obtain this information and use it to create their own estimated acquisition cost. The CMS, however, could determine its own methodology for estimating acquisition cost based upon AMP plus some mark-up percentage to compensate wholesalers and pharmacies. Under the condition that CMS does not reveal its EAC formula, AMP would remain confidential. The CMS could then report EAC data to States along with the unit rebate information it already reports on a quarterly basis.

While this option may limit State flexibility to determine their own payment systems, it would allow the States and the Federal Government to access significant program savings. In order to maintain some level of flexibility, CMS could implement this suggestion using aggregate reimbursement limits for States. This would require that total State spending on drugs did not exceed a maximum set by CMS, without imposing a strict ceiling on each prescription drug price. This approach would afford States and physicians some flexibility on a case by case basis while also providing the Federal Government with the needed oversight and control over expenditures.

- **Option 3: Share average manufacturer price data with States so that they can accurately set Medicaid reimbursement rates**

The rebate program requires drug manufacturers to report average manufacturer price and Best Price data to the Secretary in order to have their drugs reimbursed by Medicaid. Both AMP and Best Price are confidential. The confidentiality provision mandates that AMP and Best Price information provided by the manufacturer "will not be disclosed by the Secretary or State Medicaid agency in

a form which reveals the Manufacturer, or prices charged by the Manufacturer" except as necessary to carry out the Medicaid rebate program.²¹

Currently, CMS interprets the confidentiality clause very narrowly. This interpretation prevents CMS from sharing average manufacturer price data with State Medicaid agencies. The CMS reports only the unit rebate amounts to States, from which States cannot deduce AMP because of the complex unit rebate methodology. It would seem plausible, however, to interpret the confidentiality provision more broadly as a safeguard to prevent manufacturers from gaining access to the pricing information of their competitors. The legislation specifically prohibits the State Medicaid agencies from disclosing average manufacturer price and Best Price, which implies a legislative assumption that State Medicaid agencies would have access to that information. In September 1995, CMS addressed this issue in response to comments received on the proposed rule regarding Medicaid payment for outpatient drugs. The CMS asserted that they would not disclose AMP to the States but maintained that the statute contemplates the disclosure of manufacturer pricing data to the States and that they believed Congress intended that States have access to sufficient pricing information to implement the Medicaid drug rebate program.²²

Furthermore, the statute also indicates that State Medicaid agencies have a legal obligation to protect manufacturers' confidentiality interests. The CMS could initiate this reimbursement option by working with the States to devise a means of protecting the confidentiality of average manufacturer price. For example, the State Medicaid agencies could conduct in-house calculations of reimbursement for antiretrovirals using AMP plus a markup percentage that would be kept confidential. Because this methodology would only affect 16 drugs, performing and protecting this calculation should not present a formidable burden. Once CMS and the States have agreed upon protection measures, then CMS could provide AMP data to the States on a quarterly basis.

By sharing AMP information with the State Medicaid agencies, CMS could provide States with the means to fulfill the intent of the Medicaid reimbursement to reflect actual acquisition costs. Improving the accuracy of State estimates would also generate program savings. Furthermore, States would maintain flexibility in determining their reimbursement formulas and enjoy more valid information upon which to base those determinations.

Examining the Current Medicaid Dispensing Fees

Regardless of which option CMS chooses to improve pharmacy reimbursement methodology, any change should include a separate consideration of appropriate dispensing fees to ensure that pharmacists can cover their professional costs. Otherwise, pharmacies may begin to refuse Medicaid patients, limiting access for beneficiaries.

In the past, CMS has expressed concern about fair pharmacy compensation for serving Medicaid clients and has stated that one means to ensure access was to permit pharmacies to profit from sales to Medicaid clients. Though the final rule of 1987 deleted a procedural requirement for States' determination of reasonable dispensing fees, CMS expressed the expectation that the States would continue their customary activities to establish this fee. These activities included: 1) audits and surveys of pharmacy operational costs; 2) compilation of data regarding professional salaries and fees; and 3) analysis of compiled data regarding pharmacy overhead costs, profits, etc. We recommend that CMS consider reinstating the requirement that States determine a reasonable dispensing fee using one of the methods described or another appropriate method for estimating pharmacy dispensing costs.

The Centers for Medicare and Medicaid Services should initiate a review of Medicaid rebates for the 16 HIV/AIDS drugs examined

Though an improved reimbursement methodology would generate program savings, it would not completely close the gap between Medicaid and other government drug purchasers. Medicaid reimbursement cannot be lowered so far as to eliminate all pharmacy profit without risking pharmacies' willingness to serve this population. This access concern limits the extent to which decreased reimbursement can achieve savings.

However, the Medicaid rebate program could significantly increase the unit rebate amount and still allow the manufacturers to profit from participation. Drug manufacturers receive approximately 76 percent of the cost of a prescription. After deducting taxes, research, marketing and other operational costs from this gross share, manufacturers retain a net profit that averages over 18 percent.

Initiating a review of the rebate formula to address the purchasing disadvantage that Medicaid faces in comparison to other Federal purchasers would be consistent with the legislative history of the program. The Omnibus Budget Reconciliation Act of 1990 created the Medicaid drug rebate program and set forth a formula based upon average manufacturer price and Best Price. This formula produced an unintended consequence that disadvantaged certain Federal drug purchasers, including the VA. The Veterans Health Care Act of 1992 amended the rebate program to correct that disadvantage. Congress changed the rebate formula to exclude certain government purchasers from the Best Price calculation in order to secure better drug prices for those programs. The VHCA of 1992 also increased the rebate percentage from 12.5 percent to 15.7 percent off of AMP in the last quarter of 1992 and then incrementally lowered it to 15.1 percent.

We propose that CMS examine how another legislative amendment could ameliorate Medicaid's purchasing disadvantage to generate program savings for the 16 drugs examined. We offer two suggestions for further research, which are linked to the

reimbursement option that CMS pursues. If CMS chooses to base reimbursement calculations upon average manufacturer price, as outlined by either Option 2 or Option 3 of the previous recommendation, then we suggest the following:

► **Option 1: Increase the rebate percentage of average manufacturer price**

Ensuring that Medicaid's net costs more closely resemble the costs of other Federal purchasers requires an increase in the Medicaid unit rebate. The current Medicaid rebate is statutorily based upon a 15.1 percent discount off of AMP.²³ One of the reasons that the Federal ceiling price is much lower than the Medicaid net price is because the Federal ceiling price statutorily receives a 24 percent discount off of average manufacturer price. Regardless of improvements to the reimbursement formula, the Medicaid net price would still exceed the Federal ceiling price because the Federal ceiling price receives a greater discount off of average manufacturer price. Increasing the percentage off of AMP used for the rebate calculation would allow Medicaid to access greater program savings.

On the other hand, if CMS continues to base reimbursement on average wholesale price, as outlined by Option 1 of the reimbursement recommendations, then we suggest the following:

► **Option 2: Base rebates on average wholesale price rather than average manufacturer price**

Another potential means to achieve these savings involves changing the basis of the Medicaid rebate calculation from average manufacturer price (AMP) to average wholesale price (AWP). In May 1998, the OIG issued "Need to Establish Connection between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs" (A-06-97-00052). This report recommended a legislative change requiring that Medicaid rebates be based upon AWP. Despite concurring with the administrative benefits, CMS disagreed that such a proposal was feasible. We suggest that CMS re-evaluate this recommendation to determine whether it would achieve program savings.

As discussed, the current disconnection between reimbursement based on AWP and rebates based on AMP creates an incentive for manufacturers to use average wholesale price inflation as a profit-based incentive for providers to choose their drug. Using average wholesale price for rebate calculations would minimize manufacturers' incentives to inflate AWP because their rebate obligations would increase as AWP increased. Furthermore, the rebate program guarantees an additional rebate when drug prices increase at a faster rate than inflation, as measured by the consumer price index. This mechanism also discourages artificial price inflation. If Medicaid reimbursement methodology continues to use average wholesale price, then this change could both improve the accuracy of reimbursement and increase the unit rebates.

One concern, however, that CMS should consider involves this susceptibility of AWP to manipulation. Average wholesale price listings are not currently indexed to actual transactions, so conceivably, manufacturers could artificially lower AWP in the same way that they can artificially inflate it. A lower AWP could reduce Medicaid reimbursement expenditures, but it would also reduce unit rebate amounts. These circumstances complicate the forecasting of net program savings through this option.

Implications for Broader Medicaid Drug Benefit

While our findings and recommendations pertain only to antiretroviral drugs, numerous other Inspector General reports have concluded that Medicaid pays more than other Federal and private purchasers for a wide variety of drugs. In 1997, the IG estimated that the actual acquisition cost for brand name drugs averaged 18.3 percent below AWP. The difference between actual acquisition cost and generic drugs averaged 42.5 percent. For a complete list of the findings and recommendations of these reports, please consult Appendix F.

As part of a larger effort to examine the problems plaguing Medicaid drug reimbursement and rebate policies, our recommendations build off the recommendations made in previous OIG reports. Future work in this area may, in turn, find that the recommendations presented in this report for antiretrovirals drugs may have broader applicability.

A G E N C Y C O M M E N T S

The CMS provided comments on the draft report in which they agreed with the overall intent of our recommendations but expressed reservations with many of the specific suggestions we offered for achieving them. The complete text of CMS's comments can be found in Appendix E. Primarily, CMS felt that they did not have the statutory authority to make the suggested changes. Since reducing prices for HIV/AIDS medications is so crucial to ensuring access to these drugs, we encourage CMS to seek any legislation necessary to accomplish the task. However, we continue to believe that most of the options delineated in the report can be undertaken without amending current law. Below we review CMS's concerns and offer some specific suggestions on how our recommended options could be operationalized under current law.

In response to the first option related to Medicaid reimbursement, CMS stated that there are already safeguards in place to protect AWP from price manipulation. The CMS points out that the law gives States the authority to establish their own payment methodologies for prescription drugs. Consequently, CMS believes that States retain the responsibility for implementing any necessary safeguards, with CMS "encourag[ing] states to be proactive in monitoring the pharmaceutical marketplace." Finally, CMS stated that their guidance to the States regarding the calculation of estimated acquisition cost was clear and that further guidance would constitute Federal price controls.

While it is true that some safeguards protecting Medicaid from AWP inflation are in place, considerable evidence points to the fact that AWP is still very vulnerable to price manipulations. Appendix F lists several other OIG reports that, like this report, document on-going problems with AWP calculations resulting in higher prices to the Medicaid program. Federal and State prosecutors are currently investigating numerous drug companies regarding alleged inflation of AWP for Medicaid-covered drugs. In January 2001, the Bayer Corporation agreed to pay \$14 million to settle charges of alleged AWP inflation and other alleged wrongdoing. Even CMS has demonstrated an awareness of the problems with AWP validity through support of legislative proposals to replace AWP with actual acquisition cost and through correspondence with the House Commerce Committee. The persistence of these problems indicates that this issue has not yet been sufficiently addressed.

The OIG agrees that CMS should not impose price controls, and our recommendations do not suggest price controls. Rather, our options to safeguard AWP suggest that CMS provide more specificity in the guidelines that it already imposes. While we agree with CMS that States retain responsibility for defining their EAC methodology, CMS also retains the responsibility of oversight for that methodology through the State plan approval process. The CMS has demonstrated the authority to provide boundaries of acceptability of EAC calculations. In the State Medicaid Manual, CMS already requires that States must include a "significant discount" off of AWP in order for a State's

reimbursement methodology to be accepted. Given the preponderance of evidence that demonstrates AWP still overstates prices, we believe that CMS should further clarify the requirements of an acceptable use of AWP by specifying that the AWP should be derived in a way that reflects actual market transactions.

The CMS disagreed with our second option related to Medicaid reimbursement, to create a national EAC for the States based on the AMP, and our third option, to share AMP data with States to set Medicaid reimbursement rates. In both cases, they cited the statutorily protected confidentiality of AMP. The CMS did agree to examine the current dispensing fee as part of their state plan amendment review process and will do so whenever a State proposes a fee change.

We continue to believe that the creation of a national estimated acquisition cost based on AMP is workable on a drug-by-drug basis without disclosing AMP information. This recommendation applies to only 16 very specific drugs, namely, antiretrovirals to treat HIV/AIDS. We believe that the CMS could develop an estimated acquisition cost for the States for these 16 drugs based upon AMP plus a markup percentage. The CMS could share the calculated EAC for these 16 drugs without revealing the formula from which the EAC was derived much the way they currently share unit rebate amounts with States without revealing AMP.

Our interpretation of the confidentiality provision for AMP leads us to believe that CMS could legally share AMP with the State Medicaid programs. The confidentiality provision mandates that AMP information provided by the manufacturer “will not be disclosed by the Secretary or State Medicaid agency in a form which reveals the Manufacturer or prices charged by the Manufacturer.”²⁴ The specific inclusion of the State Medicaid agencies in that mandate implies a legislative assumption that those agencies would have access to AMP information. In September 1995, CMS addressed this issue and expressed an interpretation of this provision more similar to our own. In the Federal Register (60 FR 48442), CMS stated that although they would not disclose AMP to the States at that time, they maintained that the statute contemplates the disclosure of this manufacturer pricing data to the States.²⁵

Our second recommendation called for CMS to initiate a review of Medicaid rebates for the 16 HIV/AIDS drugs examined in this study. The CMS agreed with the first option of increasing the rebate percentage of AMP and plans to include this recommendation when they consider legislative changes for the Medicaid program.

The CMS disagreed with our second option, basing the rebates on AWP rather than AMP, citing comments to an OIG report from 1998, “Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs” (A-06-97-00052). In these comments, CMS stated that a legislative change was not feasible at the time the report was issued and expressed concern with AWP validity. We share this concern, and our recommendation advised CMS to consider the susceptibility of AWP to manipulation if they chose this option.

In the 1998 CMS comments, CMS stated that they were planning to examine the calculation of AWP, including issues such as, “how AWP is defined; how to safeguard against manipulation of AWPs to maximize reimbursement or minimize rebates; how to verify the accuracy of AWPs; the need for an indexing factor; and differences in AWPs for brand name versus generic drugs.”²⁶ We support such an examination. We agree that these issues warrant CMS’s attention, and these concerns strengthen our belief that the CMS should provide greater guidance to the States regarding acceptable use of AWP.

We hope that this additional discussion of our recommendations is helpful to CMS. We encourage them to reconsider the feasibility of each option to accomplish the ultimate goal of assuring that Medicaid pays reasonable prices for the 16 antiretroviral drugs we reviewed. Reducing prices for these life-saving antiretrovirals is an essential step in helping the Medicaid program meet the demands of expanded eligibility for people living with HIV.

APPENDIX A

Glossary of Terms

Estimated Acquisition Cost (EAC) — State Medicaid agency's best estimate of the price generally and currently paid by pharmacies for a drug.² This figure is meant to represent pharmacies' actual acquisition cost (AAC).

Average Wholesale Price (AWP) — The published manufacturer's suggested list price for a wholesaler to charge a pharmacy for a drug.³

Wholesale Acquisition Cost (WAC) — the price paid by the wholesaler for drugs purchased from the manufacturer. Publicly listed WAC amounts may not reflect all available discounts.⁴

Actual Acquisition Cost (AAC) — The net cost at which the pharmacy acquires a drug.⁵

Average Manufacturer Price (AMP) — The average price paid by wholesalers to the manufacturer for drugs distributed to the retail pharmacy class of trade.⁶

Best Price (BP) — The lowest price available for a drug from the manufacturer to any purchaser with the exception of Federal agencies and State pharmaceutical assistance programs.⁷

² State Medicaid Manual, Part 6, Section 6305.1

³ Prescription Drug Trends -- A Chartbook. The Henry J. Kaiser Family Foundation, July 2000.

⁴ Ibid.

⁵ Ibid.

⁶ 42 USC Sec. 1396r-8(k)(1)

⁷ 42 USC Sec. 1396r-8(c)(1)(C)

APPENDIX B

List of Antiretroviral Pharmaceuticals

Pharmaceutical	Manufacturer	Activity Class	Chemical / Mechanistic Class
Crixivan (Indinavir)	Merck	Antiviral	Protease Inhibitor
Invirase (Saquinavir)	Hoffmann-La Roche	Antiviral	Protease Inhibitor
Sustiva (Efavirenz)	DuPont	Antiviral	Non-Nucleoside Reverse Transcriptase Inhibitor
Norvir (Ritonavir)	Abbott Laboratories	Antiviral	Protease Inhibitor
Viracept (Nelfinavir)	Agouron Pharmaceuticals	Antiviral	Protease Inhibitor
Retrovir (AZT) (Zidovudine)	Glaxo Wellcome	Antiviral	Nucleoside Reverse Transcriptase Inhibitor
Epivir (3TC)	Glaxo Wellcome	Antiviral	Nucleoside Reverse Transcriptase Inhibitor
Videx (ddl)	Bristol Myers-Squibb	Antiviral	Nucleoside Reverse Transcriptase Inhibitor
D4T (Zerit)	Bristol Myers-Squibb	Antiviral	Nucleoside Reverse Transcriptase Inhibitor
Combivir (AZT/3TC)	Glaxo Wellcome	Antiviral	Nucleoside Reverse Transcriptase Inhibitor
Fortovase (Saquinavir)	Hoffmann-La Roche	Antiviral	Protease Inhibitor
Hivid (Zalcitabine, ddC)	Hoffmann-La Roche	Antiviral	Nucleoside Reverse Transcriptase Inhibitor
Viramune (Nevirapine)	Boehringer Ingelheim Pharmaceuticals, Inc/	Antiviral	Non-Nucleoside Reverse Transcriptase Inhibitor
Rescriptor (Delavirdine)	Pharmacia & Upjohn	Antiviral	Non-Nucleoside Reverse Transcriptase Inhibitor
Ziagen (abacavir)	Glaxo Wellcome	Antiviral	Nucleoside Reverse Transcriptase Inhibitor
Agenerase (amprenavir)	Glaxo Wellcome	Antiviral	Protease Inhibitor

APPENDIX C**Sampled States' Formulas for Estimating Acquisition Cost**

State	EAC Calculation
California	AWP - 5% or Direct Price ⁸
Florida	AWP - 13.25%
Georgia	AWP - 10%
Illinois	AWP - 10%
Maryland	lower of: AWP-10%, WAC+10%, Direct+10% ⁹
Massachusetts	WAC + 10%
New Jersey	AWP - 10%
New York	AWP - 10%
Pennsylvania	AWP - 10%
Texas	lower of : AWP - 15.5% or WAC + 12%

⁸ California has negotiated agreements with certain drug manufacturers to purchase drugs directly from the manufacturer. These agreements cover four of the drugs in our study, namely, Crixivan, Norvir, D4T and Rescriptor. Including these discounts, California Medicaid administrators estimate their average reimbursement formula is AWP- 12 percent.

⁹ Direct Price is the price at which the manufacturer sells directly to the pharmacy.

APPENDIX D**Sampled States' Dispensing Fees**

State	Dispensing Fee to Pharmacies
California	\$3.80
Florida	\$4.23
Georgia	\$4.33-\$4.63
Illinois	10.4% of drug cost up to \$15.40 maximum ¹⁰
Maryland	\$4.21
Massachusetts	\$2.50 + \$0.50 beneficiary co-pay
New Jersey	\$3.73-\$4.07
New York	\$3.50
Pennsylvania	\$4.00
Texas	\$5.27 + 2% of drug cost

¹⁰ For prescriptions that cost less than \$37.50, Illinois pays a flat fee of \$3.45. All of the drugs in our study cost more than \$37.50 per prescription.